

Application No.: 10/596,103

Amendment Submitted with RCE dated January 18, 2011

Reply to Office Action of August 17, 2010

Docket No.: 1848-7 PCT/US/RCE II

Page 9

REMARKS

Pursuant to the submission required under 37 CFR 1.114 for a Request for Continued Examination, Applicants respectfully request entry and consideration of the Amendment and Response submitted herewith.

STATUS OF CLAIMS

Claims 17-64 are pending. Please amend Claims 17, 21 and 24. In particular, Claims 17 and 21 have been amended to state that administration of the therapeutic agent is to a subject in need thereof. Additionally, Claim 24 has been amended to correct an obvious minor grammatical error therein. Support for the claim amendment can be found throughout the specification and in the claims as originally filed. No new matter has been added.

35 U.S.C. §102 REJECTIONS

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by either Petzelbauer (US 2004/0192596) and Petzelbauer (US 2007/0037749). Additionally, Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by WO 02/48180 published on June 20, 2002 in German (Petzelbauer).

As amended independent Claims 17 and 21 are directed to methods of treating shock in a subject in need thereof. Accordingly, the patient population is defined as those in need of treatment for shock.

As detailed in the Background of the Invention section of the instant application, “[s]hock is an acute complication of **many different pathological conditions** characterized by the inability of the cardiovascular system to maintain an adequate perfusion pressure” (Emphasis added, see, paragraph 2, first sentence). Specifically, the term “shock” is defined by MedTerms medical dictionary as follows:

Application No.: 10/596,103

Amendment Submitted with RCE dated January 18, 2011

Reply to Office Action of August 17, 2010

Docket No.: 1848-7 PCT/US/RCE II

Page 10

In medicine, shock is a critical condition brought on by a sudden drop in blood flow through the body. There is failure of the circulatory system to maintain adequate blood flow. This sharply curtails the delivery of oxygen and nutrients to vital organs. It also compromises the kidney and so curtails the removal of wastes from the body. Shock can be due to a number of different mechanisms including not enough blood volume (hypovolemic shock) and not enough output of blood by the heart (cardiogenic shock). The signs and symptoms of shock include low blood pressure (hypotension), overbreathing (hyperventilation), a weak rapid pulse, cold clammy grayish-bluish (cyanotic) skin, decreased urine flow (oliguria), and mental changes (a sense of great anxiety and foreboding, confusion and, sometimes, combativeness).

Shock is a major medical emergency. It is common after serious injury. Emergency care for shock involves keeping the patient warm and giving fluids by mouth or, preferably, intravenously.

As reflected in both the excerpt from the instant application as well as the definition of shock above, shock is a condition characterized by a reduction in blood flow that can be caused by different mechanisms.

In contrast to shock, the manifestation of inflammation is quite different. For example, the term "inflammation" is defined by MedTerms medical dictionary as follows:

A basic way in which the body reacts to infection, irritation or other injury, the key feature being redness, warmth, swelling and pain. Inflammation is now recognized as a type of nonspecific immune response.

Accordingly, the patient population treated for shock or inflammation is not necessarily the same patient population. Likewise, methods employed for treating subjects experiencing shock differs from those for treating or inhibiting inflammation.

Nowhere do any of US 2004/0192596, US 2007/0037749, WO 02/48180 disclose or suggest using the peptides claimed in the present application for the treatment of shock in a subject in

Application No.: 10/596,103

Amendment Submitted with RCE dated January 18, 2011

Reply to Office Action of August 17, 2010

Docket No.: 1848-7 PCT/US/RCE II

Page 11

need thereof. Further, a skilled artisan would not have a reasonable expectation of success in treating shock based on the disclosure of US 2004/0192596, US 2007/0037749 or WO 02/48180. Thus, the cited art cannot anticipate nor render obvious the claimed invention.

In light of the aforementioned remarks, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. §102(b) and §102(e) of Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62.

DOUBLE PATENTING REJECTIONS

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the following:

- Claims 1-4 of U.S. Patent No. **7,271,144**
- Claims 1-4 of copending Application No. **11/899,611**, now U.S. Patent No. **7,811,985**
- Claims 1-3 of U.S. Patent No. **7,494,973**
- Claims 6-7 of copending Application No. **12/121,533**
- Claims 6-7 of copending Application No. **12/121,544**
- Claims 1-2 and 4-5 of copending Application No. **12/158,670**

Upon indication of allowable subject matter, Applicants will address the need to file one or more terminal disclaimers to overcome the aforementioned obviousness-type double patenting rejections.

35 U.S.C. §103 REJECTIONS

Claims 17-32, 35-38, 41-44, 47-50, 53-56 and 59-62 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over **Petzelbauer** (WO 02/48180 published on June 20, 2002 in German) in view of **Bevec et al.** (US 2004/0122058).

Application No.: 10/596,103

Amendment Submitted with RCE dated January 18, 2011

Reply to Office Action of August 17, 2010

Docket No.: 1848-7 PCT/US/RCE II

Page 12

Claims 17-28, 30-33, 36-39, 42-45, 48-51, 54-57 and 60-63 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over **Petzelbauer** (WO 02/48180) in view of **Thurkauf et al.** (WO 02/49993).

Claims 17-28, 30-34, 36-40, 42-46, 48-52, 54-58 and 60-64 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over **Petzelbauer** (WO 02/48180) in view of **Yat et al.** (WO 94/07815).

WO 02/48180 discloses a peptide having general formula II as well as a peptide sequence (see SEQ ID NO: 11) corresponding to SEQ ID NO: 3 of the instant application and methods of treating inflammation in a subject comprising administering thereto an effective amount of a peptide having the general formula II.

As discussed in the 35 U.S.C. §102 rejections above, the manifestation of shock and inflammation differ significantly. Accordingly, a skilled artisan would not turn towards methods of treating inflammation in order to treat shock. Likewise, a skilled artisan would not have a reasonable expectation of success in treating shock based on the methods disclosed in WO 02/48180. Importantly, shock is a critical condition brought on by a sudden drop in blood flow through the body and require intervention with fast-acting medicaments whereas methods of treating inflammation are not necessarily fast-acting and oftentimes involve a prolonged treatment regimen.

Neither Bevac *et al.*, Thurkauf *et al.* nor Yat *et al.* cure the deficiency of WO 02/48180.

Accordingly, the claimed invention cannot be rendered obvious by WO 02/48180, either alone, or in combination with any of Bevac *et al.*, Thurkauf *et al.* nor Yat *et al.*

In view of the aforementioned remarks, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. §103.

Application No.: 10/596,103

Amendment Submitted with RCE dated January 18, 2011

Reply to Office Action of August 17, 2010

Docket No.: 1848-7 PCT/US/RCE II

Page 13

CONCLUSION

Applicants believe Claims 17-64 are in condition for allowance and respectfully request the same. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



Sandy Zarnic

Registration No.: 45,997

Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700